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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,945	01/09/2002	Randy R. Robinson	0610.0050001/MAC	5282
26111	7590	11/24/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				BLANCHARD, DAVID J
		ART UNIT		PAPER NUMBER
		1642		

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/040,945	ROBINSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	David J Blanchard	1642

## **Office Action Summary**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 25 October 2004.  
2a)  This action is **FINAL**.                            2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-94 is/are pending in the application.  
4a) Of the above claim(s) 7-15 and 17-94 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-6 and 16 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/29/02; 12/3/03

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

***Election/Restrictions***

1. The preliminary amendment filed 1/9/2002 has been entered in full.
2. Claims 1-94 are pending.
3. Applicant's election with traverse of Group I, claims 1-6 and 16 in the response filed 10/25/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Claims 7-15 and 17-94 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
5. Claims 1-6 and 16 are under examination. Claim 16 is being examined to the extent that the polynucleotide molecules encode (1) a heavy chain immunoglobulin molecule or a fragment thereof, linked to a polypeptide secretion signal and (2) a light chain immunoglobulin molecule linked to a polypeptide secretion signal.

***Specification***

6. The lengthy specification has not been checked to the extent necessary to identify all possible minor errors. Applicant's cooperation is requested in reviewing this application for spelling, TRADEMARKS, and the like errors.

***Sequence Requirements***

7. In order to have compact prosecution a first office action can be performed on this application, however, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Although the claims in the instant application are not drawn to specific sequences, the Figures and the disclosure contain sequences that require SEQ ID numbers. See page 67, lines 14 and 30, for example. With respect to the Figures, SEQ ID numbers may be added to the Brief Description of the Drawings in place of filing new Figures. Applicant is reminded to check the entire disclosure to ensure that the application is in sequence compliance.

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

APPLICANT IS GIVEN THE TIME ALLOTED IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six-month statutory

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period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

***Claim Objections***

8. Claim 16 is objected to because of the following informalities:

Claim 16 is dependent upon non-elected claims 7 and 10. Applicant is requested to re-write the limitations of claims 7 and 10 into claim 16.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 16, as written, does not sufficiently distinguish the antibody over antibodies as they exist naturally because claim 16 does not particularly point out any non-naturally occurring differences between the claimed heavy and light chain immunoglobulin molecules and the structure of naturally occurring antibodies. The claimed heavy and light chain immunoglobulin molecules linked to a polypeptide secretion sequence reads

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upon heavy and light chains as they are naturally synthesized in eukaryotic cells, prior to translocation across the endoplasmic reticulum membrane.

In the absence of the hand of man, the naturally occurring antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1996)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F. Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "an isolated" or "purified" polynucleotide molecule or similar language would obviate this rejection.

#### ***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 2 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention.

a. Claim 2 is indefinite for reciting "chimeric". The term "chimeric" is generic to a class of antibodies, which are products of genetic shuffling of antibody domains and other active proteins. The term "chimeric" encompasses antibodies fused to non-immunoglobulin proteins as well as antibodies fused to non-immunoglobulin proteins as

well as antibodies wherein any domain of the antibody is substituted by corresponding regions or residues of human antibodies including, but not limited to CDR grafted antibodies. In the absence of a single defined art recognized meaning for the phrase and lacking a definition of the term in the specification, one of skill in the art could not determine the metes and bounds of the claims. The specification's definition of "chimeric" (page 48) does not adequately define the term because it loosely states that the constant region would be "substantially similar to that present in the heavy chain of a natural human immunoglobulin". It is not clear what is meant by the phrase "substantially similar". "Substantially" is broad terminology. See In re Nehrenberg (CCPA 126 USPQ 383).

b. Claims 4-6 are indefinite for reciting "said heavy chain or heavy chain fragment and light chain encoding units" in claim 4. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites a single dicistronic transcription unit, which encodes a heavy chain or fragment thereof and a light chain, while dependent claim 4 recites that there are multiple "encoding units". Thus, it is unclear if (a) there are multiple "encoding units" present and (b) if the "encoding units" recited in claim 4 refer to the "dicistronic transcription unit" recited in claim 1.

c. Claim 16 is indefinite for reciting "linked" in claims 7 and 10 as it is not clear in what manner the linkage occurs. Would the secretion signal be covalently attached to the amino terminus of the immunoglobulin molecule so that it can function as a secretion signal or would the secretion signal be chemically conjugated to some other

portion of the immunoglobulin molecule in a manner that precludes its use as a secretion signal?

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding an antibody and an antibody fragment that binds antigen, does not reasonably provide enablement for a polynucleotide encoding an antibody or antibody fragment that only has a heavy chain fragment and a light chain and does not bind antigen as broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the

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breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to a polynucleotide encoding an antibody and an antibody fragment that only has a heavy chain fragment and a light chain that do not bind antigen. The claims do not require that the encoded antibody 'bind antigen'.

The specification discloses only polynucleotides encoding antibodies that comprise both a heavy chain immunoglobulin and a light chain immunoglobulin and the antibodies bind antigen. The specification does not enable polynucleotides encoding antibodies or antibody fragments that only have a heavy chain fragment and a light chain and do not bind antigen.

It is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding

function as evidenced by Rudikoff et al (Proc. Natl. Acad. Sci. USA 1982 Vol. 79 page 1979). Rudikoff et al teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that antibody fragments that only have a fragment of a heavy chain immunoglobulin and a light chain immunoglobulin as defined by the claim, which would contain less than the full complement of CDRs from the heavy and light chain variable regions of an antibody have the required binding function. The specification provides no direction or guidance regarding how to produce antibodies that only have a fragment of a heavy chain immunoglobulin and a light chain immunoglobulin and bind antigen as broadly defined by the claim. Further, a fragment of the heavy chain can be any one of the constant regions (CH1-3) and also may be the hinge region. However, the language also reads on small amino acid sequences, which are incomplete regions of the constant region of the antibody. One of skill in the art would neither expect nor predict the appropriate functioning of the antibody encoded by the polynucleotide as broadly as is claimed. Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

Thus, one of skill in the art would not know how to use antibodies or antibody fragments that do not bind antigen and undue experimentation would indeed be required to produce the invention commensurate with the scope of the claims from the written disclosure alone.

***Priority***

15. The effective filing date of the instant application is deemed to be the filing date of parent application USSN 07/501,092, i.e., 3/29/1990. It is noted that priority applications USSNs 06/793,980, 07/077,528 and 07/142,039 are not available to the examiner at this time. Therefore, the examiner could not determine whether the instant claims have priority to said applications. PCT/US86/02269 (WO 87/02671) does not apparently provide support for all of the instantly claimed limitations. It is also noted that USSN 06/793,980 and USSN 07/077,528 do not share copendency. If applicant desires priority prior to 3/29/1990; applicant is invited to point out and provide documentary support for the priority of the instant claims. Applicant is reminded that such priority for the instant limitations require written description and enablement under 35 U.S.C. §112, first paragraph.

***Claim Rejections - 35 USC § 102***

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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17. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by either of Wood et al (Nature. 314:446-449, April 1985, Ids reference AS52), Sharon et al (Nature. 309:364-367, May 1984, Ids reference AT43), Ochi et al (Proc. Natl. Acad. Sci. USA. 80:6351-6355, 1983, Ids reference AR35), Morrison et al (Proc. Natl. Acad. Sci. USA. 81:6851-6855, Nov. 1984, Ids reference AT30), Cabilly et al (Proc. Natl. Acad. Sci. USA. 81:3273-3277, June 1984, Ids reference AR8), or Boulianne et al (Nature. 312:643-646, December 1984, Ids reference AR7).

Claim 16 recites a polynucleotide molecule encoding a heavy chain immunoglobulin or fragment thereof, linked to a polypeptide secretion signal or a polynucleotide molecule encoding a light chain immunoglobulin linked to a polypeptide secretion signal. Due to the indefinite nature of claim 16 (see 112 2<sup>nd</sup> above), claim 16 is interpreted to mean that the secretion signal is covalently attached to the amino terminus of the immunoglobulin molecule and functions as a secretion signal. In this rejection claim 16 is interpreted as a polynucleotide molecule encoding a heavy chain linked to a polypeptide secretion signal and a polynucleotide molecule encoding a light chain linked to a polypeptide secretion signal.

a. Wood et al teach the synthesis and in vivo assembly of functional antibodies in yeast (see Title and Figure 3) wherein heavy and light chains were localized by the immunofluorescence techniques to an intracellular localization. One skilled in the art would reasonably conclude that the light and heavy chain of Wood et al are linked to a secretion signal while inside the yeast cells.

b. Sharon et al teach the expression of chimeric immunoglobulins in mouse myeloma cells and both the heavy and light chain immunoglobulins can be detected in the cytoplasmic fraction and in the secreted fraction (see Figure 2). The light and heavy chains are linked to a secretion signal prior to secretion from the mouse myeloma cell, thus the limitation of the claim has been met.

c. Ochi et al teach the production of IgM in lymphoid cells, wherein the heavy and light chains are linked to a secretion signal (see Figure 2).

d. Morrison et al teach the production of a chimeric antibody in a mouse myeloma cell line, wherein the heavy and light chains are linked to a secretion signal (see page 6854).

e. Boulianne et al teach the production of chimeric antibodies in mammalian cell lines, wherein the heavy and light chains are linked to a secretion signal (see Figure 2).

f. Cabilly et al teach heavy and light chain immunoglobulins, which are linked to a polypeptide secretion signal (see Figure 1).

18. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Early et al (Cell. 19:981-992, 1980).

Claim 16 and its interpretation has been described supra (see item 17 above). In this rejection claim 16 is interpreted as a polynucleotide encoding a heavy chain linked to a polypeptide secretion signal.

Early et al teach polynucleotide molecule encoding a phosphorylcholine heavy chain immunoglobulin molecule linked to a polypeptide secretion signal (see Figure 3 and page 984).

19. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Zemel-Dreasen et al (Gene. 27(3):315-322, 1984, lds reference AR53).

Claim 16 and its interpretation has been described supra (see item 17 above). In this rejection claim 16 is interpreted as a polynucleotide encoding a light chain linked to a polypeptide secretion signal.

Zemel-Dreasen et al teach the secretion and processing of the entire L-321 light chain. Zemel-Dreasen et al teach plasmids containing the entire coding sequence of L-321 including the signal peptide (pTI27) and/or the  $\beta$ -lactamase signal peptide (pRI12/B13) (see Figures 3 and 1) and the polypeptides were secreted (see Table 1 and pages 320-321). It is the examiner's position that any immunoglobulin chain, which is secreted from a host cell must have had, prior to secretion, a secretion signal.

20. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Gillies et al (Cell. 33:717-728, 1983, lds reference AR15).

Claim 16 and its interpretation has been described supra (see item 17 above). In this rejection claim 16 is interpreted as a polynucleotide encoding a heavy chain linked to a polypeptide secretion signal.

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Gillies et al teach the expression of the immunoglobulin heavy chain (see Figure 2). It is the examiner's position that any immunoglobulin chain, which is secreted from a host cell must have had, prior to secretion, a secretion signal.

21. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Skerra et al (Science. 240:1038-1041, May 1988, lds reference AR45).

Claim 16 and its interpretation has been described supra. (see item 17 above). In this rejection claim 16 is interpreted as a polynucleotide molecule encoding a heavy chain linked to a polypeptide secretion signal and a polynucleotide molecule encoding a variable light chain and a variable heavy chain linked to a polypeptide secretion signal.

Skerra et al teach a polynucleotide encoding the variable domains (Fv) of the phosphorylcholine-binding antibody McPC603 that was secreted into the periplasmic space (i.e., contained a polypeptide secretion signal) in E.coli and was able to bind antigen (see abstract).

22. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Better et al (Science. 240:1041-1043, May 1988, lds reference AR5).

Claim 16 and its interpretation has been described supra. (see item 17 above). In this rejection claim 16 is interpreted as a polynucleotide molecule encoding a heavy chain linked to a polypeptide secretion signal and a polynucleotide molecule encoding a variable light chain and a variable heavy chain linked to a polypeptide secretion signal.

Skerra et al teach a polynucleotide encoding an active chimeric Fab specific for the human carcinoma cell line C3347 that was secreted into the periplasmic space (i.e., contained a polypeptide secretion signal) (see pages 1041-1042).

23. Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Cabilly et al (U.S. patent 4,816,567, filed 4/8/1983, Ids reference P05).

Claim 16 and its interpretation has been described supra. (see item 17 above). In this rejection claim 16 is interpreted as a polynucleotide molecule encoding a heavy chain linked to a polypeptide secretion signal and a polynucleotide molecule encoding a light chain linked to a polypeptide secretion signal.

Cabilly et al teach the use of a secretion signal for the expression of mature immunoglobulins, from yeast and bacteria (see column 13, lines 5-18). Thus, the limitations of claim 16 have been met.

#### ***Double Patenting***

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 1-6 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 4 of U.S. Patent 5,595,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn towards a polynucleotide comprising a prokaryotic promoter region operably linked to a dicistronic transcription unit encoding a heavy chain immunoglobulin or fragment thereof and a light chain immunoglobulin, wherein the immunoglobulins are chimeric and the heavy and light chain encoding units are separately operably linked to a pectate lyase signal peptide useful for prokaryotic secretion and a polynucleotide molecule encoding a heavy chain immunoglobulin or fragment thereof linked to a polypeptide secretion signal or a light chain immunoglobulin linked to a polypeptide secretion signal. U.S. Patent 5,595,898 is drawn to a vector comprising a polynucleotide molecule encoding an immunoglobulin fragment comprising a first and second DNA, wherein the first DNA sequence encodes an immunoglobulin Fd molecule or fragment thereof comprising the variable region and the second DNA sequence encodes an immunoglobulin light chain or fragment thereof comprising the variable region, wherein said immunoglobulin Fd molecule and said immunoglobulin light chain are selected such that the resulting immunoglobulin fragment is chimeric and the immunoglobulin Fd and the

immunoglobulin light chain DNA encoding sequences are separately operably linked to a pectate lyase secretion signal sequence (i.e., first and second pectate lyase secretion signal sequence) and are operably linked to a single prokaryotic promoter so as to form a dicistronic transcription unit, wherein the immunoglobulin fragment is produced and secreted by an *E. coli* host and is capable of binding to an antigen.

Because claims 1-6 and 16 are drawn to a genus and the claims in U.S. Patent 5,595,898 are drawn to a species, the genus reads on the species and the claims in the Patent anticipate the instant claims.

***Conclusion***

26. No claim is allowed.
27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

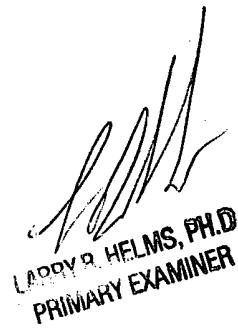
Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
David J. Blanchard  
571-272-0827



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER